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Title: A Method And A Device For The Manufacturing Of Ear Pieces

A method and a device for the manufacturing of ear pieces

The present invention relates to a method and a device for the manufacturing of ear pieces, and more particularly to custom made ear pieces, denominated "tailored plugs".

It is well-known that ear pieces may be used for a range of purposes, such as hearing protectors provided with integrated accessories such as damper elements; as part of a hearing aid or as a housing for a communication means, e.g. a loud speaker, a microphone or the like.

Ear pieces must be adapted individually to each user, as the auditory meatus is individually shaped for each person.

In the prior art, this has been achieved by making an impression of the auditory meatus. Thus, initially a plug of cotton wool is placed in the auditory meatus, whereupon a casting compound, preferably silicone or similar, is injected into the auditory meatus. The setting of the casting compound provides a cast model, which provides a reproduction of the auditory meatus. This cast is used for the manufacturing of a counter-model. Finally, a synthetic resin, preferably acrylate, is poured into the void of the counter-model. The hardened resin finally provides the ear plug.

This prior art method is very complicated. It is labor intensive, and in case a substantial number of hearing protectors are requested for the employees of a company, skilled people have to go there to make impressions at substantial cost. In addition there is the risk of hurting the tympanic membrane due to the injection of casting compound or due to the removal of the set model, in particular in case a vacuum is created during the removal.

The invention provides a method and a device for the manufacturing of ear pieces, which avoids the above mentioned problems.

In a first aspect, the invention provides a method for the manufacturing of ear pieces, which is characterized by comprising the three dimensional establishment of the

shape of the auditory meatus of the patient or other person, and the manufacturing of the respective ear plug based on the results of the establishment.

The three dimensional establishment of the shape of the auditory meatus by a measuring technique achieves the advantage of avoiding the requirement of making an impression of the ear of the patient, which results in considerable savings in manipulations and time and the elimination of any risk of hurting the tympanic membrane. The results of the tracings permit storing the shape of the auditory meatus in a database without any need for storing the actual model impressions.

The establishment as well as the manufacturing may take place in a variety of ways, as will be described in the detailed part of the specification.

The invention further provides an apparatus for the implementation of the above-mentioned method, which is characterized by comprising the combination of a tracing apparatus for a three-dimensional tracing of the shape of the auditory meatus and a manufacturing device for the transformation of the tracings, possible post-processed, into an ear piece.

For the purpose of more clearly illustrating the invention some preferred embodiments shall be described in the following with reference to the accompanying drawings, in which:
Fig. 1 schematically depicts the method according to the invention;
Fig. 2 illustrates the ear piece according to Fig. 1, placed in the auditory meatus of the respective patient or similar;
Fig. 3 and 4 schematically depicts two approaches for the three-dimensional tracing of the auditory meatus;
Figs. 5, 6 and 7 depicts various sensors, by which the tracing may be carried out;
Figs. 8 and 9 schematically depicts two further approaches for the three-dimensional tracing of the auditory meatus;
Figs. 10 and 11 schematically depicts two approaches for the manufacturing of the ear pieces based on the results of the tracing; and
Figs. 12 to 15 depicts a variety of ear pieces manufactured by the method according to the invention.

As schematically depicted in Fig. 1, the method according to the invention mainly comprises a three-dimensional tracing 1 of the shape of the auditory meatus 2 of a patient 3 or similar, or at least of part of the auditory meatus 2, and of the subsequent manufacturing, based on the resulting data 4, of an ear piece 5, which then, as depicted in Fig. 2, precisely matches the respective auditory meatus 2.

The tracing 1 is performed by means of a tracing device 6, which may be of various kinds, as will be explained in the following.

The tracing data retrieved 4 may optionally be intermediately stored in a data storage 7, preferably a computer, which will also make it possible to adapt details, or to add details, preferably such as the length of the ear piece 5 to be manufactured. Thus the tracing data 4 may easily be stored in an information carrier, such as a magnetic disk, whereby the tracing data of a substantial number of patients or similar may easily be shipped from the site, where the tracing has been conducted, to the site of the manufacturing, in the event these sites are not adjacent.

The manufacturing takes place by use of a manufacturing device 8.

During manufacturing, the ear piece 5 is preferably formed directly as an end product. However, as depicted schematically in Fig. 1, this does not exclude the manufacturing of an intermediate 9 model based on the tracing results 4, and subsequently a negative model 10, for the purpose of manufacturing subsequently the ear piece 5A, by means of the negative model. Although this approach involves a greater number of steps than the direct manufacturing of the ear piece 5, it may be useful in case the ear piece 5A has to be manufactured in a material, which cannot be manufactured directly by means of the manufacturing device 8.

According to a variant embodiment, schematically referenced 11, the tracing data 4 may be used in the manufacturing of a negative model 10, whereupon the ear piece 5 may be manufactured in the classic way by means of the negative model 10.

According to the invention, the tracing of the shape of the auditory meatus 2 may take place without contact or with contact during the tracing.

For the purpose of a non-contacting tracing, the invention provides mainly three solutions, i.e.:
-a non-contacting total or "overall" scanning;
-a non-contacting local scanning;
a non-contacting scanning by means of a probe to be introduced into the auditory meatus.

According to the invention these tracing methods may be implemented by a variety of approaches, such as imaging by means of scanning and/or X-ray, scanning by means of waves, preferably ultrasound waves, magnetic waves, light, in particular laser-light or similar.

By a total or "overall" scanning, the method is carried out as shown in Fig. 3.

Hereby the tracing device 6 comprises at least a scanner 12, which makes images of thin slices 13 of the auditory meatus 2, preferably by means of so-called CT-scans (Computer Tomography). The scanning is performed at the level of the ear 14, however over the entire cross-section of the head 15 of the patient or similar. Concurrently, a tracing of both auditory meatuses of the patient may be retrieved. The tracing device 6 further comprises an image processing unit 16, by which the tracing data 4 may be retrieved from the recorded image.

The image processing unit 16 for the transformation of the image into the three-dimensional information is not necessarily a part of the tracing device 6, but may be a separate unit.

Fig. 4 schematically depicts how to implement a non-contacting scanning by means of a probe 17. The probe 17 comprises a pin 18 provided with various sensors 19. The sensing takes place by displacing the pin 18 along the auditory meatus 2, preferably by use of an actuator 20, which is part of the tracing device 6.

The sensors 19 may be of a variety of kinds. According to Fig. 4, use is made of a transmitter element 21, which transmits a signal 22, and a receiver element 23, which receives a signal 22 reflected from the wall of the auditory meatus 2. From the signal 22, the distance from the probe 17, more particularly from the transmitter element 21 to the wall of the auditory meatus 2, can be derived, preferably by recording the spot

where the reflected signal 22 impinges on the receiver element 23, or by determining the path traversed by the signal.

By twisting the probe 17, a two-dimensional tracing may be implemented. By shifting the probe 17 also in the longitudinal direction Z the tracing may assume a three-dimensional character.

During this tracing, the head 15 of the patient 3 may be rested against a support.

The probe 17 may be encased in a sleeve 24, which is transparent to the signal 22.

The signal 22 may be of a variety of kinds, and is preferably implemented by means of light, in particular laser-light, ultrasound, magnetism or the like.

As depicted in Fig. 5, the probe 17 used may comprise a line of transmitter elements 21, and preferably corresponding receiver elements 23, which are distributed around the entire circumference of the probe 17. In this way the probe 17 does not have to be twisted and has only to be shifted in the longitudinal direction.

Fig. 6 shows a variant with several transmitter elements 21 and receiver elements 23, which are distributed around the circumference as well as along the longitudinal direction Z. This probe 17 may be placed in the auditory meatus for carrying out a tracing without requiring any movement of the probe 17.

Fig. 7 shows a variant, in which the transmitter elements 21 and the receiver elements 23 are arranged in the longitudinal direction Z, whereby the probe 17 has only to be twisted for the tracing.

In a particular embodiment the probe 17 is provided with means for controlling the depth of penetration, on one side for permitting establishing a point of reference and on the other side for preventing hurting the tympanic membrane 25. A point of reference may be defined by contacting the tympanic membrane 25 by means of an intermediate material or in non-contacting way.

Fig. 8 depicts a method using a non-contacting method. A small element 26 in a plug of cotton wool 27 is placed in the auditory meatus 2, and use is made of a probe 17

provided with a magnetic proximity sensor 28, which, without contact, permits alerting when the front tip of the probe is in the vicinity of the element 26 and thus of the tympanic membrane 25.

The above-mentioned means might also comprise a proximity probe 28 relying on a different principle without requiring the presence of the element 26.

Fig. 9 depicts a tracing device 6, in which the scanner and/or the measuring elements 29-30 are integrated in an element 31 in the appearance of a head set, the element 31 being connected to a tracing device 32. This embodiment is advantageous in that such an element 31 may be dispatched to plants, whereby tracings may recorded for each person, without requiring the presence of specially trained personnel. The recorded tracings 4 may then be dispatched to the manufacturer of the ear pieces 5, 5A, who will then manufacture the required ear pieces, based on the recorded tracings 4.

For the manufacturing a variety of manufacturing devices may be used.

As a first possibility according to the invention, devices for cutting may be used. They are preferably CNC-devices. One example of these is shown in Fig. 10, in which an ear piece 5 is being manufactured from a rotating blank 33 by means of a finger milling machine 34, which may be moved in a sideways as well as in a radial direction according to the tracing data 4, or according to information derived from the tracing data 4.

Another possibility makes use of an adaptation of a method named as "Rapid prototyping", where the ear piece is systematically built in a material according to a method generally used for the making of prototypes, although with the notable modification that here the actual end product is directly manufactured rather than a prototype.

In the preferred embodiment the manufacturing device 8 comprises an apparatus for stereo lithography.

As depicted schematically in Fig. 11, in this method a liquid 35 or a powder is arranged in a reservoir 36, and at the surface 37 a layer is fused according to a well defined pattern, e.g. by means of a laser-beam 38, which is moved above the surface

37 by means of a device 39. By resting this layer on a movable support 40, and by systematically lowering the support 40 by means of an actuator 41, upon the molding of each layer, the ear piece 5 may be built layer on layer. The device 39 and the actuator 41 are hereby driven by a control unit 42 according to the recorded tracing data 4.

The liquid 35 may preferably comprise acrylate or epoxy resin, possibly with additives, such as vinyl ester. The laser may comprise an infrared laser or a helium-cadmium laser.

The above mentioned method of stereo lithography has the advantage that through passages 43 and any recesses 44 for the arrangement of accessories may be formed directly in the ear piece 5 by moving the laser beam 38 along a specific pattern, by which post processing for the arrangement of such through passages 43 and recesses 44 by drilling or cutting are not required.

Instead of producing placing layer on top of layer, it is also possible to produce layer below layer, whereby the setting systematically takes place at the low side and the ear piece 5 is displaced upwards during building.

Eventually, an ear piece as depicted in Fig. 12 is provided, wherein any accessories required may be placed. In the example in Fig. 12, the accessories comprise a small plug 45 for the sealing off of a test conduit by a control valve 46 for controlling acoustic damping. An ear piece 5 provided with such accessories is described in e.g. US patent 4,974,606.

In another embodiment, a hollow shape is manufactured by means of stereo-lithography, of which shape the wall 47, as shown in Fig. 13, matches the contour of the ear piece to be manufactured 5, whereupon the hollow shape, in order to provide the ear piece, is filled with synthetic material 48 or similar, which is set. This method has an advantage in that just small portion of material must be hardened by the stereo-lithographic process, whereby the total time for the manufacturing process is shortened considerably. Obviously, any recesses or apertures may be arranged subsequently by means of drilling or milling.

Fig. 14 illustrates a different embodiment in which the contour of the through passage 43 and the recess 44 is built by a stereo-lithographic process and the resulting void is filled by a synthetic material 48.

As illustrated in Fig. 15, it is also possible to arrange other accessories in the ear piece 5, e.g. by placing them in the hardened material during the stereo-lithographic process. In fig. 15, e.g., a vibration sensor 49 is placed in the ear piece 5, by which speech of the person carrying such an ear piece may be converted into an electric signal 50, which signal may be used for further communication.

The stereo-lithographic process also permits immediate placing during the forming of the ear piece 5 of identification insignia 51 therein, in order to personalize the ear piece 5 to distinguish it from other formed ear pieces 5, 5A in order to dispatch the correct ear piece to the respective person and in order to make a distinction between the left and the right ear piece 5.

Within the scope of the invention, also other "Rapid Modeling" methods may be used, such as "Fused Depositing Modeling", "Solid Ground Curing Technology", building by means of fusing together layers of foil, "Spin Casting" etc. The advantages of these methods is the possibility of an accuracy to a few microns.

Preferably, the ear piece 5 should be made from a non-toxic and bio-compatible, synthetic material. Such synthetic materials may be transparent or colored, and can be made in a hard or a soft synthetic material according to user preferences.

The invention relates to the above explained method as well as to apparatuses adapted for implementing this method in accordance with what has been mentioned above.

In a particular embodiment, the apparatus comprises a tracing device 6 for the tracing of the shape of the auditory meatus 2 together with an connected or a separate manufacturing device 8 by which the user may immediately be provided with his or her ear pieces 5.

The invention is in no way limited to the embodiments described and illustrated, and rather the method and the device for manufacturing of ear pieces may be implemented in different variants without departing from the scope of the invention.

Claims

1. A method for the manufacturing of ear pieces, in particular so-called tailored ear pieces, characterized by comprising a three-dimensional tracing of the shape of the auditory meatus (2), and the manufacturing in accordance with the results of the tracing (4) of respective ear pieces (5, 5A).

2. The method according to claim 1, characterized by the intermediate storage of the tracing results (4) in a data memory (7) or in a data carrier.

3. The method according to claim 1 or 2, characterized by the tracing of the auditory meatus (2) being conducted in a non-contacting way.

4. The method according to claim 3, characterized by the non-contacting tracing being conducted by any one of the below three procedures:

a non-contacting complete or "overall" scanning and deriving from the recorded picture the three-dimensional data of the auditory meatus (2);

a non-contacting local scanning and deriving from the recorded picture the three-dimensional data of the auditory meatus (2);

a non-contacting tracing by means of a probe (17) inserted in the auditory meatus (2).

5. The method according to claim 4, characterized by the tracing being conducted by any one of the below procedures:

imaging by means of a scanner;

imaging by means of an X-ray recording;

sensing by means of waves and/or light, in particular ultrasonic sound waves, magnetic waves, laser light.

6. The method according to claim 4 or 5, characterized by comprising the use of CT-scans.

7. The method according to claim 4 or 5, characterized by comprising the use of a probe (17) comprising a pin (18) provided with different sensors (19).

8. The method according to claim 7, characterized by comprising the use of a probe (17) with at least one transmitter member (21) and one receiver member (23), by which a signal (22) reflected off the wall of the auditory meatus (2) is received, whereby the distance to the wall of the auditory meatus (2) may be determined.

9. The method according to claim 7 or 8, characterized by comprising the use of one of the following probes (17):

a probe (17) with a transmitter member (21) and a receiver member (23), whereby the probe (17) is twisted and shifted along the longitudinal direction (Z), whereby the shape as well as the probe (17) motion is derived from the signal (22);

a probe (17) with peripherally arranged transmitter members (21) and receiver members (23), whereby the probe (17) for the purpose of the tracing is solely shifted along the longitudinal direction (Z);

a probe (17) provided with transmitter members (21) and receiver members (23) distributed over the entire surface;

a probe (17) with transmitter members (21) and receiver members (23) permitting the detection on a line, whereby the probe (17) for the purpose of the tracing is preferably solely twisted.

10. The method according to any of the claims 7 - 9, characterized by comprising conducting a check of the penetration depth of the probe (17).

11. The method according to any of the claims 4, 5 or 6, characterized by comprising the use of scanner members or sensing members (29-30) integrated into a member (31) in the shape of a headset.

12. The method according to any of the preceding claims, characterized by the ear pieces (5) being manufactured from a blank (33) by means of a cutting procedure performed in accordance with the tracing data (4) or in dependency of data derived from the tracing data (4).

13. The method according to any of the claims 1 - 11, characterized by comprising systematic building of the ear piece (5) by means of a so-called "Rapid Prototyping" procedure, directly adapted for the end product.

14. The method according to claim 13, characterized by the ear piece (5) being manufactured by means of a stereo-lithographic procedure.

15. The method according to claim 13, characterized by the ear piece (5) being manufactured by means of one of the following procedures;

"Fused Depositing Modeling";

"Solid Ground Curing Technology";

Building by fusing layers of foil;

"Spin Casting".

16. The method according to any of the claims 13 - 15, characterized by passages (43) and recesses (44) for the placement of accessories and the like are provided in the ear pieces (5) during the systematic building.

17. The method according to any of the claims 13 - 15, characterized by the ear pieces (5) being provided during building with identification insignia (51).

18. An apparatus for the manufacturing of ear pieces according to any of the claims 1 - 17, characterized by comprising a combination of a tracing device (6) for a three-dimensional tracing of the shape of the auditory meatus (2) and a manufacturing device (8) adapted for converting the charted, optionally post-processed, data (4) into an ear piece (5).